

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Harbige et al.	)	Group Art Unit: Not yet assigned
	)	
Application No.: 10/555,757	)	Examiner: Not yet assigned
	)	
Filed: November 7, 2006	)	
	)	
For: USE OF TRIGLYCERIDE OILS	)	Confirmation No.: 2532
CONTAINING GAMMA-	)	
LINOLENIC ACID RESIDUES AND	)	
LINOLEIC ACID RESIDUES FOR	)	
THE TREATMENT OF	)	
NEURODEGENERATIVE	)	
DISEASE	)	

**Mail Stop PCT Legal Administration**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**Renewed Petition for Filing a Declaration Under 37 C.F.R. § 1.47(a)**  
**by Applicants on Behalf of a Non-Signing Inventor**

Pursuant to 37 C.F.R. § 1.47(a), Applicants hereby renew their petition to the Commissioner to accept the accompanying declarations signed by three of the inventors, Drs. Laurence S. Harbige, Michael J. Leach, and Paul Barraclough, on behalf of the non-signing inventor, Dr. Mohammed Sharief. In accord with M.P.E.P. § 409.03(a)(A), the signature block for Dr. Sharief has been left blank on each declaration. The required statement of pertinent facts under 37 C.F.R. § 1.47(a) that Dr. Sharief either can not be reached or refuses to join in the application is set forth in the

accompanying declarations of Ms. Erika Szedon, Dr. Tariq Osman, Ms. Emma Spencer, and Mr. Paul Mussenden. Dr. Sharief's last known residence is 2-B Mainridge Road, Chislehurst, Kent, BR7 6DW England. The required fee of \$200.00 under 37 C.F.R. § 1.17(g), along with the \$ 2,230.00 fee for a five-month extension of time, is enclosed.

Applicants submitted a petition under 37 C.F.R. § 1.47(a) to accept the declarations of the three signing inventors on behalf of Dr. Sharief on February 22, 2007. *Szedon Declaration* at 8 (Exhibit E). A Statement by Ms. Szedon accompanied the petition and set forth the facts of her meeting with Dr. Sharief in person on November 28, 2006. *Id.* (Exhibit D). At that meeting, after previous mailings to him of the declaration and assignment for this application on February 24, 2006, and August 11, 2006, Ms. Szedon offered another copy of those documents for him to execute. *Id.* at 6. Dr. Sharief refused to sign the documents at that time and referred Ms. Szedon to his solicitor, Ms. Ensor, who was present at the meeting. *Id.* at 7.

In the Decision on Petition dated March 8, 2007, the Attorney Advisor alleged that it was unclear whether Dr. Sharief had been presented with a copy of the application specification when the declaration and assignment were offered to him for execution. *Id.* (Exhibit F). As M.P.E.P. § 409.03(d) requires that a copy of the specification be presented to the non-signing inventor before a refusal to join can be established, the Office denied Applicants' petition without prejudice. The Office allowed a two month period in which Applicants could petition for reconsideration, with extensions of time available under 37 C.F.R. § 1.136(a). Accordingly, Applicants submit that the present renewed petition under 37 C.F.R. § 1.47(a) is timely filed.

Applicants submit that Dr. Sharief is obligated to assign the invention of the present application (Serial No. 10/555,757, “the ‘757 application”) to BTG International Limited (“BTG”) by virtue of an Assignment Agreement (“AA”) dated July 30, 2002, (Attachment 1) and a Confirmatory Assignment Agreement (“CAA”) (Attachment 2) dated September 30, 2003, both agreements being between the University of Greenwich, King’s College London, BTG, and Drs. Harbige, Leach, and Sharief (as the “INVENTORS”; see, e.g., Schedule 1 of the AA). In the AA (Clause 2.1), Dr. Sharief assigned to BTG his rights in the INVENTION described in Confidential Schedule 2, which corresponds to the inventions disclosed and claimed in the ‘757 application. Dr. Sharief also agreed to assist BTG in obtaining protection of the INVENTION in jurisdictions of BTG’s choosing, including the execution of documents necessary to obtain such protection. (Clause 3.1.)

The CAA similarly confers the obligation on Dr. Sharief to assign his rights to the inventions of the ‘757 application and to cooperate in the their prosecution, which includes executing such documents as an oath or declaration. Specifically, the CAA refers to the AA, in which the INVENTORS Harbige, Leach, and Sharief, defined at Paragraph 4, p. 3 and Schedule 1, assigned inventions (referred to as ESSENTIALLY RELATED INVENTIONS, CAA, p. 3) to BTG and agreed to assign to BTG certain further inventions (referred to as FURTHER INVENTIONS, CAA at p. 3). The CAA equates ESSENTIALLY RELATED INVENTIONS with FURTHER INVENTIONS. (CAA, p. 3, Clause (D)). The CAA contemplates the assignment of both the ESSENTIALLY RELATED INVENTIONS with FURTHER INVENTIONS to BTG at Clause 2.1 and its

subsections. (CAA, p. 6). The CAA at p. 11 generally describes the inventions subject to assignment at Confidential Schedule 2, and the invention of the '757 application falls within the scope of "Invention A" as described. (CAA, p. 11). Finally, the CAA requires Dr. Sharief to assist BTG in obtaining the grant of patent or other protection for the inventions in any territory as may be chosen by BTG. CAA at p. 6, Clause 3.1.1. Indeed, Dr. Sharief specifically agreed to "execute and do all such documents, acts and things that may be necessary" for the purposes of the CAA. CAA at p. 7, Clause 3.1.2.

Of course, in the United States, one such act required for a U.S. patent application is the execution of a declaration under 37 C.F.R. § 1.63 in satisfaction of 35 U.S.C. § 115. M.P.E.P. § 602.

However, as described below, Dr. Sharief to date has failed to execute a § 1.63 declaration in this application. Applicants respectfully submit that given obligations of Dr. Sharief, as set forth in the AA and the CAA, Dr. Sharief's failure and refusal to execute a declaration for this application renders the grant of this Petition necessary to preserve the rights of all of the parties in the '757 application.

The Office provides a mechanism by which signing inventors may make a declaration on behalf of a non-signing inventor if certain conditions are met as set forth in 37 C.F.R. §1.47 and M.P.E.P. § 409.03. M.P.E.P. § 409.03(d) requires that the circumstances of the presentation of the application papers and of the refusal be specified in a statement of facts by the person to whom the refusal was made and documentary evidence to support the facts, if any, be submitted, as well as the non-signing inventor's reasons, if any, for refusing to sign the declaration. In the present

application, Ms. Erika Szedon, Dr. Tariq Osman, Ms. Emma Spencer, and Mr. Paul Mussenden were the persons who attempted to reach Dr. Sharief for the purpose of having him execute his declaration for the present application. They have submitted declarations in support of this Petition that set forth their efforts in this regard.

On March 12, 2007, after the denial of the original Petition under Rule 1.47(a), Mr. Mussenden sent Ms. Ensor (Dr. Sharief's legal representative) an email. In the email, he indicated that he wished to speak with Dr. Sharief about a scientific project, but did not mention the need for his execution of the declaration in the '757 application. *Mussenden Declaration* at 4. Ms. Ensor indicated that she had forwarded the message on to Dr. Sharief, but that she could do no more than to forward the message to Dr. Sharief. *Id.* at 5. Dr. Sharief did not contact Mr. Mussenden in response to this inquiry. *Id.*

Given Ms. Ensor's aid in forwarding messages to Dr. Sharief, Ms. Szedon sent a copy of the '757 specification, along with a copy of the '757 declaration and assignment, by recorded delivery to Ms. Ensor on April 19, 2007. *Szedon Declaration* at 10. Applicants submit that this mailing of the specification and declaration satisfies the requirements of M.P.E.P. § 409.03(d). Her cover letter described the earlier petition's defects identified in the Decision on Petition and asked that Ms. Ensor forward the documents to Dr. Sharief at his home address for his execution. *Id.* (Exhibit H). She asked that Dr. Sharief execute and return the documents to Ms. Murphy at BTG by May 1, 2007, or alternatively, provide a written statement that he refused to sign them. *Id.*

As this package was seemingly lost in the mail, Ms. Szedon resent the package to Ms. Ensor on May 15, 2007. *Id.*

Ms. Ensor confirmed that she had received the May 15, 2007, mailing and had forwarded it to Dr. Sharief. *Id.* at 11. However, Ms. Ensor indicated that she could not be of further assistance in contacting Dr. Sharief. *Id.* Thus, on June 13, 2007, Dr. Osman attempted to telephone Dr. Sharief at his office.<sup>1</sup> *Osman Declaration* at 6. However, his messages were not returned. *Id.* Ms. Spencer also tried to reach Dr. Sharief by telephone at his home in late June, 2007, but he did not return her messages either. *Spencer Declaration* at 4.

On July 25, 2007, Dr. Osman mailed a copy of the '757 declaration and the '757 application to Sharief at his work address and asked him to execute the declaration. *Osman Declaration* at 7. The documents were sent by United Postal Service ("UPS"). *Id.* While UPS confirmed receipt by Colchester Hospital, Dr. Sharief did not respond. *Id.* (Exhibit D).

On September 4, 2007, Ms. Szedon sent a letter to Dr. Sharief at his home address by courier enclosing a copy of the '757 declaration and '757 specification. *Szedon Declaration* at 12. Dr. Sharief was asked to execute the declaration and assignment, and return it to Ms. Murphy no later than September 28, 2007. *Id.* A return form was provided in the letter where Dr. Sharief could indicate his receipt of the

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<sup>1</sup> Dr. Sharief left the College's employment in December, 2006. *Szedon Declaration* at 2. As of June, 2007, Dr. Osman was aware that Dr. Sharief was employed at Colchester General Hospital. *Osman Declaration* at 3.

documents and whether he chose or declined to execute them. *Id.* (Exhibit L). Three attempts were made to deliver this package by courier without success. *Id.* at 13.

Ms. Szedon then had a colleague send a copy of the September 4, 2007, package to Dr. Sharief's home address by standard mail on September 14, 2007. *Id.* Her colleague's cover letter reiterated Ms. Szedon's requests that Dr. Sharief execute and return the documents, or otherwise indicate his refusal on the enclosed form. *Id.*, Exhibit N. To date, Dr. Sharief has not responded to any of the attempts described above to execute the '757 application by signing the '757 declaration, or even to return the declarants' phone calls.

Thus, since his oral refusal to Ms. Szedon during the November 28, 2006, meeting, Dr. Sharief has effectively been unable to be reached by the diligent efforts of the four declarants over a nearly 10 month period. Applicants have incurred the expense of the maximum number of extensions of time for replying to the Decision on Petition to afford Dr. Sharief every opportunity to respond to their requests for his execution of the '757 declaration. The ample period afforded to Dr. Sharief for responding at the expense of Applicants illustrates the good faith of Applicants' inquiries and attempts to have Dr. Sharief fulfill his obligations to execute the '757 application by signing the '757 declaration. By failing to respond to all such inquiries and attempts, Dr. Sharief has constructively refused to join in this application.

Applicants submit that all the requirements of 37 C.F.R. § 1.47(a) and M.P.E.P. § 409.03 have been met. Accordingly, Applicants request that the Commissioner approve this petition and the accompanying Declarations of the three signing inventors

as fulfilling the requirement under 37 C.F.R § 1.63 to file a proper Declaration or Oath in the present application.

If there are any other fees required for filing this paper, including any fees for extensions of time, please charge these fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.



By: Reg. No. 57,404  
Bryan Diner  
Reg. No. 32,409

Dated: October 9, 2007



# **ATTACHMENT 1**

Leg-5  
143,884

DATED 30 JULY 2002

UNIVERSITY OF GREENWICH

- and -

KING'S COLLEGE LONDON

- and -

BTG INTERNATIONAL LIMITED

- and -

certain INVENTORS named  
in the attached Schedule

ASSIGNMENT AGREEMENT  
of inventions relating to preparations of oils  
and other rights

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THIS ASSIGNMENT is made as a deed on 30 July 2002

BETWEEN:

1. THE UNIVERSITY OF GREENWICH, a company limited by guarantee, incorporated in England and Wales, of Old Royal Naval College, Park Row, Greenwich, London SE10 9LS ("UG"); and
2. KING'S COLLEGE LONDON, an institution incorporated by Royal Charter, of Strand, London WC2R 2LS, England ("KCL"); and
3. BTG INTERNATIONAL LIMITED whose company registration number in England and Wales is 2664412 and whose registered office is at 10 Fleet Place, Limeburner Lane, London EC4M 7SB, England ("BTG", including its successors and assigns); and
4. the inventors whose names and addresses are set out in Schedule 1 to this Agreement (together the "INVENTORS" and each an "INVENTOR").

WHEREAS:

UG, KCL and the INVENTORS have each agreed to assign to BTG certain inventions, together with other rights and intellectual property (if any) on the terms of a Revenue-Sharing Agreement made between UG, KCL, the INVENTORS and BTG and dated the same date as this Agreement.

NOW THIS DEED WITNESSETH as follows:

1. DEFINITIONS

1.1 In this Agreement the definitions below shall have the following meanings:

"COPYRIGHT"	such existing and future copyright, arising from the work of any of: (a) the INVENTORS; or (b) the research groups under the direction of any of the INVENTORS, throughout the world as is currently, or may in the future be, vested in UG and/or KCL and/or the INVENTORS (or any of them) and which subsists in the INVENTIONS and the KNOW-HOW;
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"EFFECTIVE DATE"	the date of this Agreement;
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"ESSENTIALLY RELATED  
INVENTION AND/OR  
KNOW-HOW"

any existing or further invention and/or know-how which are essentially related to the INVENTIONS, of which UG and/or KCL and/or the INVENTORS (or any of them) is or becomes proprietor, and which UG and/or KCL and/or the INVENTORS (or any of them) is or becomes free to assign to BTG without encumbrances, and which is disclosed to BTG with the intent that such invention and/or know-how shall be included in an application by BTG which application claims priority from any application made in respect to the INVENTIONS under the Patents Act 1977 or any International Convention or Treaty;

"FORMULATIONS"

such existing and future forms and formulations of the oils identified in Schedule 2 arising from the work of any of (a) the INVENTORS; or (b) the research groups under the direction of any of the INVENTORS, throughout the world as are currently, or may in the future be, vested in UG and/or KCL and/or the INVENTORS (or any of them) and which subsist in the INVENTIONS (or any of them) and which UG and/or KCL and/or the INVENTORS (or any of them) is or becomes free to assign to BTG without encumbrances;

"INVENTIONS"

means the inventions which are described in Confidential Schedule 2 to this Agreement arising from the work of any of the INVENTORS;

"IPR"

the INVENTIONS (or any of them), the COPYRIGHT, the FORMULATIONS, the KNOW-HOW, and any other rights (other than any relevant moral rights);

"KNOW-HOW"

such existing and future know-how, including but not limited to notes, techniques, processes, formulae, experimentation results, drawings, models, prototypes, designs, computer software, technical information and data, and calculations arising from the work of any of: (a) the INVENTORS; or (b) the research groups under the direction of any of the INVENTORS, throughout the world as are currently, or may in the future be, vested in UG and/or KCL and/or the INVENTORS (or any of them) and which may subsist in the INVENTIONS (or any of them);

"PATENTS"

- i) any applications for patents over the INVENTIONS and any patents which may be granted pursuant to such applications; and
- (ii) any re-issues and extensions of such patents, and any divisions and continuations of such applications;

"REVENUE-SHARING  
AGREEMENT"

the Agreement referred to in the Recital to this Agreement.

- 1.2 In this Agreement the singular shall, where the context so permits, include the plural and vice versa. Headings to clauses are added for convenience only and shall not affect the construction or interpretation of such clauses. References in this Agreement to clauses and schedule are to clauses of and schedule to this Agreement. The Schedules form part of this Agreement.

2. ASSIGNMENT AND COMMERCIALISATION

- 2.1 UG, KCL, and the INVENTORS each as to its/their respective rights and interests, hereby assigns to BTG with full title guarantee:
- 2.1.1 the IPR and all their respective rights and interests therein, together with the full, unfettered, and exclusive right to use the same for any purpose, and
  - 2.1.2 any ESSENTIALLY RELATED INVENTION AND/OR KNOW-HOW, and
  - 2.1.3 the right to apply for and obtain patent or other similar protection in any territory, or group of territories, in respect of the INVENTIONS and any other ESSENTIALLY RELATED INVENTION AND/OR KNOW-HOW.
- 2.2 Notwithstanding the provisions of clause 2.1, UG, KCL, and the INVENTORS shall retain a right to use the INVENTIONS and IPR solely for the purposes of its/their own academic teaching and non-commercial research.
- 2.3 BTG shall endeavour to secure the patenting and commercialisation of the INVENTIONS and the IPR on the terms of the REVENUE-SHARING AGREEMENT.

3. COVENANTS

3.1 UG, KCL, and the INVENTORS hereby covenant with BTG that respectively:

3.1.1 they will (so far as necessary) permit and enable BTG to apply for, and will take all reasonable steps, at the request and cost of BTG, to assist BTG in obtaining, the grant of patent or other protection for the IPR, or like protection in respect of the INVENTIONS, in any territory as may be required by BTG; and

3.1.2 they will, at the request and cost of BTG, execute and do all such documents, acts and things as may be necessary for the purposes of this Agreement; and

3.1.3 they will promptly disclose the IPR to BTG.

4. WARRANTIES

4.1 UG, KCL, and the INVENTORS hereby warrant each as to its/their respective IPR that, except as they have disclosed in writing to BTG prior to the EFFECTIVE DATE, and to the best of their knowledge and belief as at the EFFECTIVE DATE:

4.1.1 the entire right, title, and interest, in and to the INVENTIONS and the IPR are vested in UG and/or KCL and/or the INVENTORS with full title guarantee, together with all rights relating to the transferability thereof; and

4.1.2 they are each free to disclose the IPR to BTG; and

4.1.3 they have not entered into any options, agreements, or other arrangements, with third parties affecting such right, title, and interest, or the commercialisation of the INVENTIONS and the IPR; and

4.1.4 they are not aware of any facts or circumstances which might render any of the PATENTS invalid or incapable of enforcement; and

4.1.5 they are not aware that any person is entitled to call for possession or control of any of the FORMULATIONS.

- 4.2 UG, KCL, and the INVENTORS shall promptly notify BTG in writing if they become aware of any of the matters referred to in clause 4.1, insofar as they are free and able so to do.

5. PROVISION OF RELEVANT INFORMATION

- 5.1 If UG and/or KCL and/or the INVENTORS are or become aware of information relating to:

5.1.1 any use by any third party of any of the INVENTIONS and/or any of the IPR which might amount to an infringement of any of their respective rights therein, or

5.1.2 any other unauthorised use of any of the IPR;

then, in so far as they are free and able to do so, UG and/or KCL and/or the INVENTORS shall make reasonable efforts to inform BTG of such information without delay.

- 5.2 Each of UG and KCL and the INVENTORS recognise that BTG's ability to exploit the INVENTIONS and/or the IPR and/or to devise an exploitation strategy for the INVENTIONS and/or the IPR may be affected by matters other than infringement and/or any other unauthorised use of the IPR. Insofar as UG and/or KCL and/or the INVENTORS are free to do so, they will inform BTG of any such matters which come to their notice and which appear to be relevant and which are not in the public domain.

6. CONFIDENTIALITY

- 6.1 UG and KCL and the INVENTORS shall each keep the KNOW-HOW confidential, and shall not use, disclose, or part with any of the KNOW-HOW, orally or in writing, to any third party without BTG's prior written consent. These obligations, together with those under clause 6.2, shall not apply to:

6.1.1 any of the KNOW-HOW which is, or becomes, in the public domain, otherwise than by any breach of this Agreement by UG and/or KCL and/or any of the INVENTORS; or

6.1.2 any of the KNOW-HOW which is required to be disclosed or made available by UG and/or KCL and/or the INVENTORS to a third party pursuant to any applicable law, governmental regulation, or decision of any court or tribunal of competent jurisdiction, so long as UG and/or KCL and/or the INVENTORS take reasonable steps, in light of the



circumstances, to give BTG sufficient prior notice in order to contest such law, governmental regulation, or decision; or

6.2 UG and KCL and the INVENTORS (or any of them) shall not disclose or publish those INVENTIONS or any part of such INVENTIONS or those ESSENTIALLY RELATED INVENTIONS or any part of such ESSENTIALLY RELATED INVENTIONS which arise from the work of any of (a) the INVENTORS or (b) the research groups under the direction of the INVENTORS for the period while they are employees of UG or KCL without the prior written consent of BTG provided that, if UG and/or KCL and/or any INVENTOR wishes to disclose or publish such information or data:

6.2.1 UG and/or KCL and/or the applicable INVENTOR will submit the information or data to BTG in its final form; and

6.2.2 BTG will not be entitled to withhold consent against disclosure or publication for longer than 90 days (or such other period as may be agreed) from the date of submission to BTG.

7. GENERAL PROVISIONS

7.1 UG and KCL and the INVENTORS each hereby irrevocably appoint BTG as their Attorney, to execute and do any document, act, or thing which may be necessary for the purposes of clause 2.1 of this Agreement.

7.2 THIS Agreement shall be binding on, and enure to the benefit of, the successors and assigns of the respective parties, and the definitions "UG" and "KCL" and "BTG" shall be construed accordingly.

7.3 THIS Agreement shall be read and construed in accordance with, and be governed by, English law and all the parties to it submit to the non-exclusive jurisdiction of the English courts.

IN WITNESS whereof this document has been executed and delivered as a deed on the day and year first written above.

**Schedule 1**

**THE INVENTORS**

Dr L S Harbige of 40 Middleton Close, Chingford, London, E4 8EA.  
Dr M J Leach of 48 Cherry Tree Walk, West Wickham, Kent, BR4 9EF.  
Dr M Sharief of of King's College London, Strand, London WC2R 2LS.

Confidential Schedule 2

THE INVENTIONS

The use of:

gamma linolenic acid;  
linoleic acid;  
oleic acid;  
palmitic acid

and/or glycerides of gamma linolenic acid; linoleic acid; oleic acid; and palmitic acid;

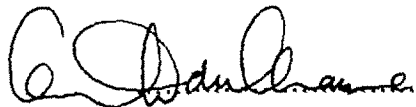
and other borage oil components

for use in elevating and/or modulating TGF $\beta$  and treating neurodegenerative conditions, particularly multiple sclerosis.

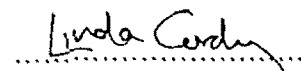
SIGNED as a DEED

by **THE UNIVERSITY OF GREENWICH**  
acting by:

)  
)  
)


  
Authorised signatory

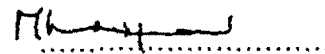
and

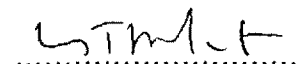
  
Authorised signatory

EXECUTED and DELIVERED as a DEED  
on behalf of **KING'S COLLEGE LONDON**  
acting by:

)  
)  
)

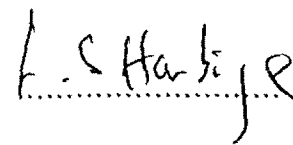
  
Authorised signatory

  
Authorised signatory

  
Authorised signatory

EXECUTED and DELIVERED as a DEED  
By **DR L S HARBIGE**  
in the presence of:

)  
)  
)



Witness signature:



Witness name:

R. BLAKEMORE

Witness address:

2 ARTHUR COTTAGES  
STREETLEY, BERKS RG7

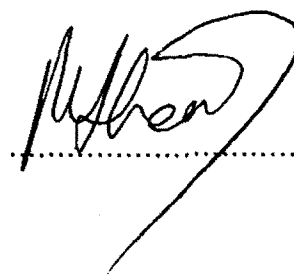
Witness occupation:

MANAGER

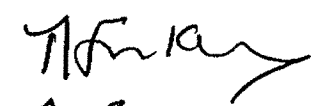
EXECUTED and DELIVERED as a DEED )

By DR M J LEACH )

in the presence of: )



Witness signature:



Witness name:

A FRANKEL

Witness address:

96 C LAURISTON RD  
LONDON E9 7HA

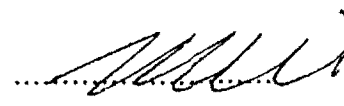
Witness occupation:

LAWYER

EXECUTED and DELIVERED as a DEED )

By DR M SHARIEF )

in the presence of: )



Witness signature:

S Bennett

Witness name:

SHARRON BENNETT

Witness address:

57 KLEA AVE  
LONDON SW4 9HY

Witness occupation:

TECHNOLOGY TRANSFER EXECUTIVE

EXECUTED and DELIVERED as a DEED )

On behalf of BTG INTERNATIONAL LIMITED )

acting by: )



Director/authorised signatory



Secretary/authorised signatory

# **ATTACHMENT 2**

THIS CONFIRMATORY ASSIGNMENT AGREEMENT WITH THE  
UNIVERSITY OF GREENWICH AND KING'S COLLEGE LONDON  
APPLIES TO THE FOLLOWING

143884 BORAGE OIL FOR NEURODEGENERATION

500134 STRUCTURED LIPIDS

THIS ASSIGNMENT is made as a deed on 30<sup>th</sup> September 2003

BETWEEN:

1. THE UNIVERSITY OF GREENWICH, a company limited by guarantee, incorporated in England and Wales, of Old Royal Naval College, Park Row, Greenwich, London SE10 9LS ("UG"); and
2. KING'S COLLEGE LONDON, an institution incorporated by Royal Charter, of Strand, London WC2R 2LS, England ("KCL"); and
3. BTG INTERNATIONAL LIMITED whose company registration number in England and Wales is 2664412 and whose registered office is at 10 Fleet Place, Limeburner Lane, London EC4M 7SB, England ("BTG", including its successors and assigns); and
4. the individuals whose names and addresses are set out in Schedule 1 to this Agreement (together the "INVENTORS" and each an "INVENTOR").

WHEREAS:

- (A) By virtue of an Assignment Agreement (the "ASSIGNMENT") dated 30 July 2002 UG, KCL and the INVENTORS each agreed to assign to BTG certain inventions, together with other rights and intellectual property (if any) and to share the revenues derived from exploiting those rights on the terms of a Revenue-Sharing Agreement of the same date (the "REVENUE SHARING AGREEMENT") made between UG, KCL, the INVENTORS and BTG.
- (B) The ASSIGNMENT provides, inter alia, for the assignment of certain further inventions which are essentially related to the inventions actually assigned on 30 July 2002 ("ESSENTIALLY RELATED INVENTIONS").
- (C) Dr Harbige and Dr Leach have now created further inventions (the "FURTHER INVENTIONS") which build upon the previous inventions created by Dr Harbige, Dr Leach, and Dr Sharief (the "INVENTORS") assigned on 30 July 2002. Details of these FURTHER INVENTIONS are set out in Confidential Schedule 2.
- (D) The parties to this AGREEMENT wish to confirm that they deem the FURTHER INVENTIONS to be ESSENTIALLY RELATED INVENTIONS and that as such they are effectively assigned to



BTG under clause 2.1.2 of the ASSIGNMENT and the proceeds of the commercialisation of these FURTHER INVENTIONS shared on the terms of the REVENUE SHARING AGREEMENT.

- (E) Notwithstanding (D), the parties wish, by this AGREEMENT, to confirm the assignment of the FURTHER INVENTIONS on the terms of the ASSIGNMENT and to confirm that revenues derived from commercialising the FURTHER INVENTIONS will be shared on the terms of the REVENUE SHARING AGREEMENT.

NOW THIS DEED WITNESSETH as follows:

1. DEFINITIONS

1.1 In this Agreement the definitions below shall have the following meanings:

"AGREEMENT" means this Agreement;

"COPYRIGHT" such existing and future copyright, arising from the work of any of: (a) the INVENTORS; or (b) the research groups under the direction of any of the INVENTORS, throughout the world as is currently, or may in the future be, vested in UG and/or KCL and/or the INVENTORS (or any of them) and which subsists in the FURTHER INVENTIONS and the KNOW-HOW;

"EFFECTIVE DATE" the date of this AGREEMENT;

"ESSENTIALLY RELATED INVENTION AND/OR KNOW-HOW" any existing or further invention and/or know-how which are essentially related to the FURTHER INVENTIONS, of which UG and/or KCL and/or the INVENTORS (or any of them) is or becomes proprietor, and which UG and/or KCL and/or the INVENTORS (or any of them) is or becomes free to assign to BTG without encumbrances, and which is disclosed to BTG with the intent that such invention and/or know-how shall be included in an application by BTG which application claims priority from any application made in respect to the FURTHER INVENTIONS under the Patents Act 1977 or any International Convention or Treaty;

"FORMULATIONS" such existing and future forms and formulations of the oils identified in Schedule 2 arising from the work of any of (a) the INVENTORS; or (b) the research groups under the direction of any of the INVENTORS, throughout the world as are currently, or may in the future be, vested in UG and/or KCL and/or the INVENTORS (or any of them) and which subsist in the FURTHER INVENTIONS (or any of them) and which UG and/or KCL and/or the INVENTORS (or any of them) is or becomes free to assign to BTG without encumbrances;

"FURTHER INVENTIONS" means the inventions which are described in Confidential Schedule 2 to this Agreement arising from the work of any of the INVENTORS;

"IPR" the FURTHER INVENTIONS (or any of them), the COPYRIGHT, the FORMULATIONS, the KNOW-HOW, and any other rights (other than any relevant moral rights);

"KNOW-HOW" such existing and future know-how, including but not limited to notes, techniques, processes, formulae, experimentation results, drawings, models, prototypes designs, computer software, technical information and data, and calculations arising from the work of any of: (a) the INVENTORS; or (b) the research groups under the direction of any of the INVENTORS, throughout the world as are currently, or may in the future be, vested in UG and/or KCL and/or the INVENTORS (or any of them) and which may subsist in the FURTHER INVENTIONS (or any of them);

"PATENTS" i) any applications for patents over the FURTHER INVENTIONS and any patents which may be granted pursuant to such applications; and  
(ii) any re-issues and extensions of such patents, and any divisions and continuations of such applications.

1.2 In this Agreement the singular shall, where the context so permits, include the plural and vice versa. Headings to clauses are added for convenience only and shall not affect the construction or interpretation of such clauses. References in this Agreement to clauses and schedule are to clauses

of and schedule to this Agreement. The Schedules and Recitals form part of this Agreement.

- 1.3 Capitalised terms used in this Agreement which are not defined in this Agreement shall have the meanings ascribed to them in the ASSIGNMENT and the REVENUE SHARING AGREEMENT.

## 2. ASSIGNMENT AND COMMERCIALISATION

- 2.1 UG, KCL, and the INVENTORS each as to its/their respective rights and interests, hereby assigns to BTG with full title guarantee:

2.1.1 the IPR and all their respective rights and interests therein, together with the full, unfettered, and exclusive right to use the same for any purpose, and

2.1.2 any ESSENTIALLY RELATED INVENTION AND/OR KNOW-HOW, and

2.1.3 the right to apply for and obtain patent or other similar protection in any territory, or group of territories, in respect of the FURTHER INVENTIONS and any other ESSENTIALLY RELATED INVENTION AND/OR KNOW-HOW.

- 2.2 Notwithstanding the provisions of clause 2.1, UG, KCL, and the INVENTORS shall retain a right to use the FURTHER INVENTIONS and IPR solely for the purposes of its/their own academic teaching and non-commercial research.

- 2.3 BTG shall endeavour to secure the patenting and commercialisation of the FURTHER INVENTIONS and the IPR on the terms of the REVENUE-SHARING AGREEMENT.

## 3. COVENANTS

- 3.1 UG, KCL, and the INVENTORS hereby covenant with BTG that respectively:

3.1.1 they will (so far as necessary) permit and enable BTG to apply for, and will take all reasonable steps, at the request and cost of BTG, to assist BTG in obtaining, the grant of patent or other protection for the IPR, or like protection in respect of the FURTHER INVENTIONS, in any territory as may be required by BTG; and

3.1.2 they will, at the request and cost of BTG, execute and do all such documents, acts and things as may be necessary for the purposes of this AGREEMENT; and

3.1.3 they will promptly disclose the IPR to BTG.

#### 4. WARRANTIES

4.1 UG, KCL, and the INVENTORS hereby warrant each as to its/their respective IPR that, except as they have disclosed in writing to BTG prior to the EFFECTIVE DATE, and to the best of their knowledge and belief as at the EFFECTIVE DATE:

4.1.1 the entire right, title, and interest, in and to the FURTHER INVENTIONS and the IPR are vested in UG and/or KCL and/or the INVENTORS with full title guarantee, together with all rights relating to the transferability thereof; and

4.1.2 they are each free to disclose the IPR to BTG; and

4.1.3 they have not entered into any options, agreements, or other arrangements, with third parties affecting such right, title, and interest, or the commercialisation of the FURTHER INVENTIONS and the IPR; and

4.1.4 they are not aware of any facts or circumstances which might render any of the PATENTS invalid or incapable of enforcement; and

4.1.5 they are not aware that any person is entitled to call for possession or control of any of the FORMULATIONS.

4.2 UG, KCL, and the INVENTORS shall promptly notify BTG in writing if they become aware of any of the matters referred to in clause 4.1, insofar as they are free and able so to do.

#### 5. PROVISION OF RELEVANT INFORMATION

5.1 If UG and/or KCL and/or the INVENTORS are or become aware of information relating to:

5.1.1 any use by any third party of any of the FURTHER INVENTIONS and/or any of the IPR which might amount to an infringement of any of their respective rights therein, or

5.1.2 any other unauthorised use of any of the IPR;

then, in so far as they are free and able to do so, UG and/or KCL and/or the INVENTORS shall make reasonable efforts to inform BTG of such information without delay.

5.2 Each of UG and KCL and the INVENTORS recognise that BTG's ability to exploit the FURTHER INVENTIONS and/or the IPR and/or to devise an exploitation strategy for the FURTHER INVENTIONS and/or the IPR may be affected by matters other than infringement and/or any other unauthorised use of the IPR. Insofar as UG and/or KCL and/or the INVENTORS are free to do so, they will inform BTG of any such matters which come to their notice and which appear to be relevant and which are not in the public domain.

## 6. CONFIDENTIALITY

6.1 UG and KCL and the INVENTORS shall each keep the KNOW-HOW confidential, and shall not use, disclose, or part with any of the KNOW-HOW, orally or in writing, to any third party without BTG's prior written consent. These obligations, together with those under clause 6.2, shall not apply to:

6.1.1 any of the KNOW-HOW which is, or becomes, in the public domain, otherwise than by any breach of this Agreement by UG and/or KCL and/or any of the INVENTORS; or

6.1.2 any of the KNOW-HOW which is required to be disclosed or made available by UG and/or KCL and/or the INVENTORS to a third party pursuant to any applicable law, governmental regulation, or decision of any court or tribunal of competent jurisdiction, so long as UG and/or KCL and/or the INVENTORS take reasonable steps, in light of the circumstances, to give BTG sufficient prior notice in order to contest such law, governmental regulation, or decision; or

6.2 UG and KCL and the INVENTORS (or any of them) shall not disclose or publish those FURTHER INVENTIONS or any part of such FURTHER INVENTIONS or those

ESSENTIALLY RELATED INVENTIONS or any part of such ESSENTIALLY RELATED INVENTIONS which arise from the work of any of (a) the INVENTORS or (b) the research groups under the direction of the INVENTORS for the period while they are employees of UG or KCL without the prior written consent of BTG provided that, if UG and/or KCL and/or any INVENTOR wishes to disclose or publish such information or data:

6.2.1 UG and/or KCL and/or the applicable INVENTOR will submit the information or data to BTG in its final form; and

6.2.2 BTG will not be entitled to withhold consent against disclosure or publication for longer than 90 days (or such other period as may be agreed) from the date of submission to BTG.

## 7. GENERAL PROVISIONS

7.1 UG and KCL and the INVENTORS each hereby irrevocably appoint BTG as their Attorney, to execute and do any document, act, or thing which may be necessary for the purposes of clause 2.1 of this AGREEMENT.

7.2 This AGREEMENT shall be binding on, and enure to the benefit of, the successors and assigns of the respective parties, and the definitions "UG" and "KCL" and "BTG" shall be construed accordingly.

7.3 This AGREEMENT shall be read and construed in accordance with, and be governed by, English law and all the parties to it submit to the non-exclusive jurisdiction of the English courts.

IN WITNESS whereof this document has been executed and delivered as a deed on the day and year first written above.

**Schedule 1**

**THE INVENTORS**

Dr L S Harbige of 40 Middleton Close, Chingford, London, E4 8EA.  
Dr M J Leach of 48 Cherry Tree Walk, West Wickham, Kent, BR4 9EF.  
Dr M Sharief of of King's College London, Strand, London WC2R 2LS.

Confidential Schedule 2

THE INVENTIONS

Invention A:

The use of triglycerides of gamma linolenic acid, dihomo-gamma linolenic acid, and arachidonic acid for use in elevating and/or modulating TGF $\beta$  and treating neurodegenerative conditions, particularly multiple sclerosis.

Invention B:

Triglycerides as in Invention A, but also including residues of other fatty acids including oleic acid and saturated acids for use in elevating and/or modulating TGF $\beta$  and treating neurodegenerative conditions, particularly multiple sclerosis.

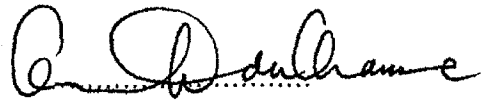
Invention C:

The use of triglycerides where at least one of the side chains comprises any of the fatty acids listed in Invention A or Invention B and where at least one side chain is phosphocholine for use in elevating and/or modulating TGF $\beta$  and treating neurodegenerative conditions, particularly multiple sclerosis.



SIGNED as a DEED  
by THE UNIVERSITY OF GREENWICH  
acting by:

)  
)  
)



Authorised signatory

and



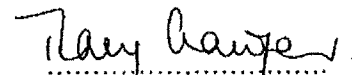
Authorised signatory

EXECUTED and DELIVERED as a DEED  
on behalf of KING'S COLLEGE LONDON  
acting by:

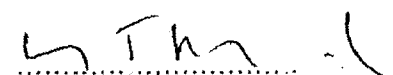
)  
)  
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Authorised signatory



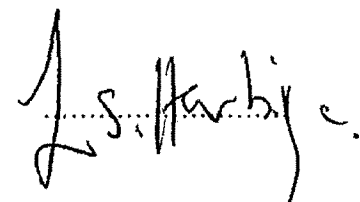
Authorised signatory




Authorised signatory

EXECUTED and DELIVERED as a DEED  
By DR L S HARBIGE  
in the presence of:

)  
)  
)



Witness signature: 

Witness name: MINGYAN XIANG

Witness address: 9 Perry Street,  
Chatham, Kent

Witness occupation: ME4 6XA  
post-doctor Research fellow

EXECUTED and DELIVERED as a DEED )

By DR M J LEACH )

in the presence of: )

Witness signature:



Witness name: RACHEL CLARK

Witness address: 22 GARDLEY ROAD

BELVEDERE

LEOT, DATA BHA

Witness occupation:

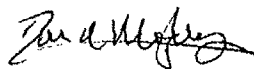
Secretary

EXECUTED and DELIVERED as a DEED )

By DR M SHARIEF )

in the presence of: )

Witness signature:



Witness name: DAVID MOZLEY

22 Backfield

Witness address:

Wootton Hill

Hastings GU27 1NA

Witness occupation: I.P. Administrator.

EXECUTED and DELIVERED as a DEED )

On behalf of BTG INTERNATIONAL LIMITED )

acting by. )



Director/authorised signatory



Secretary/authorised signatory